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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,051	10/21/2003	Motoji Sasaki	MTM-0214	3393

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EXAMINER
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HOPKINS, CHRISTINE D

ART UNIT	PAPER NUMBER
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3735

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/689,051

Applicant(s)

SASAKI ET AL.

Examiner

Christine D. Hopkins

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☒ Claim(s) 5 and 6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>21 October 2003</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "controller controlling" as disclosed in claim 3 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Objections***

2. Claims 5 and 6 are objected to because of the following informalities: “the dispensing method according to claim 1 or 2” as recited in claim 5, and “the dispensing apparatus according to claim 3 or 4” as recited in claim 6. It is unclear as to whether or not the intention was to compose a multiple dependent claim in both instances. Hence, the format is improper. Refer to MPEP 608.01(n) for an example of the proper claim format for a multiple dependent claim. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 7 discloses “a third detector detecting attenuation in the radioactivity concentration of the radioactive liquid and/or a passage of the radioactive liquid, provided to the channel of the radioactive liquid.” It is unclear as to which element above the applicant refers to with introduction of the “and/or” modifier.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

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granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Reilly (U.S. Pub. No. US 2003/0004463 A1). Reilly teaches a system and method for dispensing hazardous pharmaceutical substances. In reference to claim 1, Reilly teaches a method for accurately measuring the radioactivity levels of a dosage within a syringe, via a dose calibrator, for dispensing or delivering to a patient (col. 2, [0021] and col. 4, [0034, 0035]).

With respect to claim 2, Reilly provides a method where a component to detect radioactivity is connected to a line through which the radiopharmaceutical (i.e., radioactive liquid) is dispensed (col. 2, [0021]). In regards to claim 3, Reilly discloses a dose calibrator that measures the radiation of the radiopharmaceutical that will be subsequently dispensed under the accurate control of a powered injector (col. 6, [0064]).

In accordance with claim 4, Reilly provides for a dose calibrator adapted to measure the level of radioactivity of the pharmaceutical within a syringe (i.e. "tube constituting a channel of the radioactive liquid"). Refer to col. 3, [0024].

In reference to claim 5, Reilly teaches a method for dispensing radioactive liquid (see rejection of claim 1 supra) into a pressurizing device (syringe which contains the radiopharmaceutical) that is shielded (col. 2, [0020]), the radioactivity of the radiopharmaceutical measured, and followed by delivery to the patient (col. 2, [0021]).

With respect to claim 6, Reilly discloses a system for dispensing radioactive

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liquid (see rejection of claim 3 supra) that includes a protective container (i.e., liquid holding part) to house the radiopharmaceutical that is placed in operative proximity to a second radioactivity detector (refer to elements 570 and 570' of Figures 5C and 5D) to measure the level of radioactivity of the pharmaceutical within the enclosure, and an additional fluid path connected to the patient for delivery of the pharmaceutical (col. 2-3, [0022]).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly (U.S. Pub. No. US 2003/0004463 A1) in view of Dietzel (U.S. Patent No. 5,166,526).

Reilly discloses the invention and methods as claimed, see rejection supra, which incorporate multiple detectors (a dose calibrator and a radioactivity detector), however Reilly does not teach a third detector for detecting attenuation in the radioactivity concentration of the radioactive liquid.

Dietzel teaches an apparatus and method for measuring the radioactivity of an eluate by a flow-through detector arrangement at a high sensitivity. Several embodiments of Dietzel disclose multiple detectors, while at least one is taught to measure the radioactivity of the eluate in a stationary manner to decrease the statistical error

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associated with radioactivity measurements (col. 2, lines 9-22). In addition, Dietzel provides for multiple flow paths, wherein at least one detector, and more than one in a further embodiment, (col. 4, lines 1-2) are provided to these paths. Moreover, since Applicant has not set forth any criticality for "a third detector", it would have been obvious to one having ordinary skill in the art, at the time of the invention, to have incorporated a third detector to the system of Reilly to detect radioactivity levels of the radioactive liquids in multiple fluid delivery paths as taught by Dietzel.

Applicant is also reminded that arguments toward the criticality of an element will generally be given little patentable weight. The basis for criticality should be clearly disclosed in the specification or supplied by affidavit. See In re Cole, 140 USPQ 230 (CCPA 1964).

### ***Conclusion***

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 5,475,969 to Hardie discloses an apparatus for dispensing and monitoring a substance deemed to be biologically hazardous at three separate intervals.

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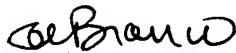
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine D. Hopkins whose telephone number is (571) 272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Christine D Hopkins  
Examiner  
Art Unit 3735

CDH

  
**PATRICIA BIANCO**  
**PRIMARY EXAMINER**  
4-12-06